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PATENT  
Customer No. 22,852  
Attorney Docket No. 07787.0042

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: )  
)  
James J. MOND et al. ) Group Art Unit: 1645  
)  
Serial No.: 09/874,991 ) Examiner: Nita M. Minnifield  
)  
Filed: June 7, 2001 ) Confirmation No.: 5537  
)  
For: IMMUNOSTIMULATORY )  
RNA/DNA HYBRID MOLECULES )

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**RESPONSE TO RESTRICTION AND ELECTION OF SPECIES REQUIREMENTS**

In the Office Action dated May 13, 2004, the Examiner required restriction under  
35 U.S.C. § 121 between:

- Group I - Claims 1-10, allegedly drawn to a composition, classified in class 536, subclass 25.6;
- Group II - Claim 11, allegedly drawn to a vaccine comprising DNA and RNA, classified in class 514, subclass 44;
- Group III - Claim 12, allegedly drawn to a method of stimulating innate immunity comprising administering RNA and DNA, classified in class 514, subclass 44;
- Group IV - Claim 13, allegedly drawn to a method of stimulating global immunity comprising administering RNA and DNA, classified in class 514, subclass 44;
- Group V - Claim 14, allegedly drawn to a vaccine comprising RNA, DNA and at least one target antigen, classified in class 514, subclass 44;
- Group VI - Claims 15 and 16, allegedly drawn to a method of stimulating cellular or humoral immune response comprising administering at

least one oligonucleotide (RNA and DNA) and at least one target antigen, classified in class 514, subclass 44; and

Group VII - Claim 17, allegedly drawn to a method of making a vaccine, classified in class 536, subclass 25.3.

In response, Applicants provisionally elect to prosecute Group I, claims 1-10, with traverse.

The Examiner also required election of up to ten (10) species from SEQ ID NOS: 1-620 for examination. In response, Applicants provisionally elect SEQ ID NOS: 2, 5, 6, 7, and 12-17, with traverse.

### **Traversal of Restriction Requirement**

In support of the requirement of restriction between Groups I, II, and V, the Examiner states that “[t]he claims of Group I are drawn to an oligonucleotide comprising both RNA and DNA, [the claims] of Group II are drawn to an oligonucleotide comprising both RNA and DNA and a physiological carrier or delivery system, [and the claims] of Group V [are drawn] to an oligonucleotide comprising both RNA and DNA and a target antigen.” (Office Action at pages 3-4.) The Examiner then contends that this statement supports the conclusion that the inventions are distinct and asserts that restriction is therefore proper. (Office Action at page 4.) Applicants respectfully disagree, and submit that this requirement is improper.

For a restriction requirement to be proper, the Examiner must show (1) that the inventions defined by the restricted groups of claims are independent and distinct, and (2) that there would be a serious burden on the Examiner if restriction was not required. M.P.E.P. § 803. The Examiner has focused on only the first part of this two-part test. In order to properly restrict the groups, the Examiner needs to show that there would be a serious burden in examining the claims together.

Applicants submit that no such serious burden exists, and respectfully submit that withdrawal of the restriction requirement as to the claims of Groups I, II, and V is appropriate. Specifically, because the claims of each group are directed to compositions comprising at least one oligonucleotide comprising both an RNA region and a DNA region, wherein at least one terminus of the oligonucleotide comprises RNA, this subject matter must be searched for each group. Thus, a thorough search and examination of Groups I, II, and V together does not represent an undue burden and Applicants respectfully request that the Examiner reconsider this restriction requirement. See M.P.E.P. § 803 ("If the search and examination of the entire application can be made without serious burden, the examiner *must* examine it on the merits, even though it includes claims to independent or distinct inventions." (emphasis added)).

Applicants expressly reserve their right, under M.P.E.P. § 821.04, to add method claims to this application that depend from, or otherwise incorporate all limitations of, the product claims of Groups I, II, and V for rejoinder with allowed product claims in this application.

#### **Traversal of Election of Species Requirement**

Applicants note that claims 1-17 do not recite specific sequences. Accordingly, applicants respectfully submit that these claims, which are generic to any sequence meeting the limitations of the claims, be fully examined in this application.

#### **Conclusion**

Applicants respectfully request the timely entry of this response and the examination and allowance of pending claims 1-17. Please grant any extensions of

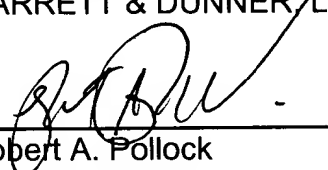
time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: June 10, 2004

By: \_\_\_\_\_

  
Robert A. Pollock  
Reg. No. 43,008